REISSUE LITIGATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of: U.S. Patent No. 5,750,338 Mark L. Collins *et al.* Reissue Serial No. 09/533,906 Reissue Application Filed: March 8, 2000 For: TARGET AND BACKGROUND CAPTURE METHODS WITH AMPLIFICATION FOR AFFINITY ASSAYS	Group Art Unit: 1655 Examiner: Johannsen, D.B.

INFORMATION DISCLOSURE STATEMENT ACCOMPANYING PROTEST UNDER 37 C.F.R. § 1.291

ATTENTION: REISSUE LITIGATION BOX 7
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with 37 C.F.R. § 1.291(a), Protestor submits with the protest: (1) a listing of patents and publications relied upon (in form PTO/SB/08), (2) a concise explanation of the relevance of each listed item, and (3) copies of each listed patent and publication.

Cited Art and Concise Explanations Thereof

Pollet et al. (1967) "Replication of Viral RNA, XV. Purification and properties of Qß minus strands" ***Proc. Natl. Acad. Sci. USA*** **58 (2): 766-773**: disclose a method of purifying a target polynucleotide (bacteriophage Qß "minus" strands) using a solid support that binds the target polynucleotide. This reference combined with Feix et al. (see below) make the claimed invention obvious.

Feix et al. (1968) "Replication of Viral RNA, XVI. Enzymatic synthesis of infectious viral RNA with noninfectious Qß minus strands as template" ***Proc. Natl. Acad. Sci. USA*** **59 (1): 145-152**: disclose an *in vitro* method of nucleic acid amplification that synthesizes increased amounts of RNA from a template RNA, the purified Qß "minus" strands (prepared using Pollet et al.'s method with some modifications), by using a polymerase, Qß replicase. The amplified RNA was detected as radioactively labeled RNA and as infectious units in a transfection assay. This reference alone anticipates the claimed invention, and combined with Pollet et al. (see above) makes the claimed invention obvious.

Chu et al., U.S. Patent No. 4,957,858 (priority date April 16, 1986): disclose methods for detecting nucleic acids by using a reporter group (RNA) that is amplified *in vitro* by a polymerase, Qβ replicase. The *in vitro* amplification method is typically carried out on a processed specimen, e.g., nucleic acids isolated from a specimen and deposited onto solid supports by using a variety of known methods (see column 7, lines 10-17 and 24-38). This reference provides the motivation to combine references that make the claimed invention obvious to one skilled in the art at the time the invention was made.

U.S. Patent 4,965,188, Mullis et al., (filed June 17, 1987): discloses an *in vitro* method, the polymerase chain reaction (PCR), for amplification of nucleic acids by using a polymerase. This method was known to one skilled in the art at the time the claimed invention was made, thus making the claimed invention obvious when combined with known methods of target polynucleotide purification as described by Chu et al.

Dattagupta et al., U.S. Patent No. 4,724,202: disclose signal amplification methods that use sandwich hybridization between a separation probe immobilized to a solid support, a target

polynucleotide, and a labeled oligonucleotide probe that includes an enzyme label that converts the enzyme's substrate into a detectable amplified signal (e.g., see column 2, line 57 to column 3, line 9). Dattagupta et al. provide motivation to combine methods that use a solid support to bind a target polynucleotide with methods that increase the detectable signal, to indicate the presence of the target polynucleotide in the sample because this provides "greater sensitivity" to the assay (see column 8, lines 35-39). Signal amplification is encompassed by Applicant's definition of "amplify" (column 2, lines 9-19), so this related art is relevant to the "amplifying" step and provides motivation to one skilled in the art to combine known methods that bind a target polynucleotide in a sample to a support with known methods of nucleic acid amplification to produce the advantages of producing more detectable signal.

Dattagupta et al., U.S. Patent No. 4,737,454 disclose nucleic acid detection methods in which a target nucleic acid is immobilized on a solid support and detected with an oligonucleotide probe labeled with an enzymatically active group to provide the advantages of signal amplification (see column 5, lines 11-22 and column 8, lines 27-31). Signal amplification is encompassed by Applicant's definition of "amplify" (column 2, lines 9-19), so this related art is relevant to the "amplifying" step and provides motivation to one skilled in the art to combine known methods that bind a target polynucleotide to a support with known methods of nucleic acid amplification to produce the advantages of producing more detectable signal in an assay.

Schneider et al., U.S. Patent No. 4,882,269, disclose an amplified hybridization assay in which a "target DNA is allowed to anneal to an immobilized sequence that does not interfere with the binding of a primary probe, and the immobilized target is contacted with the primary probe and a family of secondary probes", to provide "an enormously amplified signal" (see

Abstract and column 15, lines 62-68). Signal amplification is encompassed by Applicant's definition of "amplify" (column 2, lines 9-19), and this related art provides motivation to one skilled in the art to combine known methods that bind a target polynucleotide in a sample to a support with known methods of nucleic acid amplification to produce the advantages of producing an amplified detectable signal in an assay.

Stuart et al., U.S. Patent No. 4,732,847: disclose methods in which antibodies to bind a target polynucleotide to a support to separate it from the sample and detection of the target polynucleotide by using antibodies that amplify the number of labels (see Abstract and column 4, lines 52-55). This related art provides motivation to one skilled in the art to combine known methods to bind a target polynucleotide to a support to separate the target from the sample with known methods of nucleic acid amplification to produce the advantages of producing an amplified detectable signal in a nucleic acid assay.

D.V. Morrissey & M.L. Collins (1989) "Nucleic acid hybridization assays employing dA-tailed capture probes. Single capture methods." ***Molec. Cell. Probes*** **3: 189-207**: discloses hybridization assays in which a capture probe is immobilized on a support and used to separate target nucleic acids from sample impurities prior to detection, to provide specificity and reduce backgrounds in the assays (see Abstract and "CONCLUSIONS"). In the "ACKNOWLEDGEMENTS" section, the authors, including M.L. Collins, acknowledge "Scott Decker for adapting the PCR to our method of doing target capture", thus raising the question of whether Scott Decker should be named as an inventor of Applicant's claimed invention.

W.R. Hunsaker, H. Badri, M. Lombardo and M.L. Collins (1989) "Nucleic Acid Hybridization Assays Employing dA-Tailed Capture Probes. II. Advanced Multiple Capture Methods" ***Analytical Biochem.*** **181: 360-370**: disclose assays in which "reversible target capture" (RTC) is used to separate a target nucleic acid on a support from sample impurities. In the "DISCUSSION" the authors state that "A technique combining signal or target amplification with reversible target capture should provide the greatest possible signal with a minimum of assay noise" (see page 369, column 2). And in the "ACKNOWLEDGMENTS" (page 370), the authors, including M.L. Collins, "thank Scott Decker for showing how RTC and PCR can be successfully combined." This again raises the question of whether Scott Decker should be named an inventor of Applicant's claimed invention.

J.D. Thompson, S. Decker, D. Haines, R.S. Collins, M. Field and D. Gillespie (1989) "Enzymatic Amplification of RNA Purified from Crude Cell Lysate by Reversible Target Capture" ***Clin. Chem.*** **35/9: 1878-1881** discloses procedures in target polynucleotide are purified using "reversible target capture" followed by PCR amplification, showing that Scott Decker and others did indeed combine target capture with *in vitro* nucleic acid amplification.

This publication, together with the Morrissey and Collins, and Hunsaker et al. publications, raise the question whether Scott Decker also is an inventor of Applicant's claimed invention.

Respectfully submitted,

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